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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,890	11/20/2000	David N. S. Hon	460-001 Cont.IV	5003
22465	7590	01/20/2004		
PITTS AND BRITTIAN P C P O BOX 51295 KNOXVILLE, TN 37950-1295			EXAMINER PATTEN, PATRICIA A	
			ART UNIT 1654	PAPER NUMBER
DATE MAILED: 01/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,890	Applicant(s) HON ET AL.	
	Examiner Patricia A Patten	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The finality of the previous Office Action has been withdrawn in view of new rejections set forth *infra*.

Claims 28, 30 and 31 are pending in the application.

The Amendment filed After Final rejection on 1/7/04 was fully considered and entered into the file.

Upon further lengthy consideration of the patentability of the claims, it has been found deemed that a new rejection is in order.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions as described in the Instant specification, i.e., Example 1, does not reasonably provide enablement for a

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composition comprising an active ingredient comprising the particular parts of ions as Instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

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The Examiner has found that the parts by weight as recited in the claim for some of the ions cannot be achieved. It is noted that *some* of the embodiments will work (i.e., specific examples found in the Specification).

It is deemed that even the most skilled of artisans could not achieve (make or use) an 'active ingredient of inorganic solids comprising 10-80 parts by weight of potassium ions, 0.00001-20 parts by weight of zinc ions, 0.01-10 parts by weight of calcium ions and rubidium ions in an amount of up to 40 parts by weight for the following reasons:

The claim states that the 'active ingredient' is in the form of an 'organic solid'. The claim further requires particular amounts of ions in said solid. Applicant is referred to the table below which is a representative example of the claimed invention.

parts by weight	Ion	Ion MW	Counter ion MW	Counter ion MW
			Cl ⁻	SO ₄ ²⁻
10-80	K ⁺	39.01	35.45	43
0.0001-20	Zn ²⁺	65.39	70.90	96
0.01-10	Ca ²⁺	40.08	70.90	96
∞-40	Rb ⁺	85.48	35.45	48

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Please note again that claim 28 states 'inorganic *solids*' (emphasis added). Because potassium (K^+) forms ionic bonds with the counter ions, these counter ions are always in association with K^+ in the solid form. For example, if there were 100 mg of an inorganic solid containing 80 parts of K^+ , K^+ would be present at 80 parts or 80mg. Since this compound is a solid, the counter ion must necessarily be present at about 80 mg to form KCl. This is necessarily impossible because the composition only weighs 100 mg. Therefore, even if K^+ were the *only ion in the solid*, it could only be present at approximately 50 parts per hundred parts of the inorganic solid.

The Instant specification does not teach one skilled in the art how to make or use a composition which contains 10-80 parts by weight of potassium ions in combination with the other ions in the claims. The skilled artisan would not have any reasonable expectation of success since it is clear that creating a composition with these *ranges* of ions cannot be done.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 28 is confusing because it is not absolutely clear that 'parts by weight' is referring to the active ingredient or the composition as a whole. Applicant is asked to amend the claim in order to clearly convey if this is parts by weight of the active ingredient (or inorganic solids) or by weight of the composition in order to overcome this rejection.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

01/13/03

Patricia A Patten
Examiner
Art Unit 1654



**PATRICIA PATTEN
PATENT EXAMINER**